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Attachment 4

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the StarLux™ is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant: Palomar Medical Technologies, Inc.

Address: 82 Cambridge St.
Burlington, MA 01803
781-993-2300

Contact Person: Marcy Moore

Telephone: 919-363-2432

Preparation Date: April 22, 2004

Device Trade Name: Palomar StarLux™ Pulsed Light System

Common Name: StarLux™

Classification Name: Laser surgical instrument for use in General and Plastic Surgery and in Dermatology
(see: 21 CFR 878-4810).
Product Code: GEX
Panel: 79

Legally-Marketed Predicate Devices:

Palomar EsteLux (K040081)
Palomar StarLux (K033549)
Palomar SpaLight (K003886)
Lumenis IPL (K020839)

System Description:

The StarLux Pulsed Light System is a broad spectrum light-based medical device designed for a wide range of clinical applications. The StarLux offers 5 handpieces with Palomar's patented contact cooling technology, each specifically designed for the optimal treatment of specific clinical indications.

Intended Use of the Device:

The StarLux™ System is intended for treatment of inflammatory acne and for the treatment of cutaneous lesions, including warts, scars and striae.

Performance Data:

The differences in the specifications of the StarLux™ and the predicates do not result in different performance or raise new questions of safety or efficacy.

Conclusion:

Based on the foregoing, the StarLux™ pulsed light system is substantially equivalent to the legally marketed claimed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 13 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Palomar Medical Technologies, Inc.
c/o Ms. Marcy Moore
Manager of Clinical Studies
131 Kelekent Lane
Cary, North Carolina 27511

Re: K041086

Trade/Device Name: StarLux™ Pulsed Light System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 12, 2004
Received: October 21, 2004

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041086/S001

Device Name: StarLux™ Pulsed Light System

Indications for Use:

The StarLux pulsed light system is intended for the treatment of inflammatory acne (acne vulgaris) and for the treatment of benign pigmented epidermal and cutaneous lesions, including warts, scars and striae.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K041086